



ATTORNEY DOCKET NO.: 2002834-0222 (Bacterial Delivery DIV1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caplan

Examiner: Huynh

Serial No.: 10/728,051

Art Unit: 1644

Filing Date: December 4, 2003

Title: MICROBIAL DELIVERY SYSTEM

Mail Stop: Amendments  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

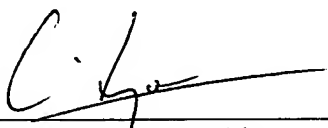
TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (2 pages);
2. Supplemental Information Disclosure Statement (5 pages);
3. Transmittal Letter (1 page);
4. Statement of Limited Recognition Under 37 CFR § 11.9(b); and
5. Return Postcard.

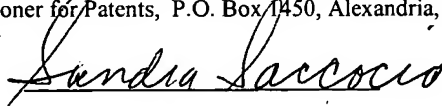
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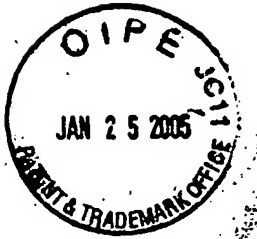
Respectfully submitted,

  
\_\_\_\_\_  
Charles E. Lyon, D.Phil  
Agent for Applicant  
Limited Recognition Under 37 CFR §11.9(b)

Choate, Hall & Stewart  
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Dated: 1/21/05

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Sandra Saccoccia	
Typed or Printed Name of person signing certificate	



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Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- [ ] An *original* Information Disclosure Statement; or  
[X] A *supplemental* Information Disclosure Statement.

**Certificate of Mailing**

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Date

1-21-05

Signature

Sandra Saccocia

Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
  - ☒ Before the mailing of a first Office action on the merits; or
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
    - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
    - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

designated in § 1.56(c) more than three months prior to the filing of  
the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under  
§ 1.113, a notice of allowance under § 1.311, or an action that otherwise closes  
prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure  
statement was first cited in any communication from a foreign  
patent office in a counterpart foreign application not more than  
three months prior to the filing of the information disclosure  
statement; or

☐ That no item of information contained in the information  
disclosure statement was cited in a communication from a foreign  
patent office in a counterpart foreign application, and, to the  
knowledge of the person signing the certification after making  
reasonable inquiry, no item of information contained in the  
information disclosure statement was known to any individual  
designated in § 1.56(c) more than three months prior to the filing of  
the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included;
- ☒ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/731,375	December 6, 2000	Published

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC §102.

It is respectfully requested that:

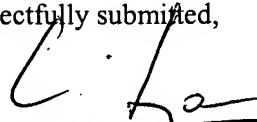
1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Dated:

1/21/05

Respectfully submitted,



Charles E. Lyon, D.Phil.  
Agent for Applicant  
Limited Recognition Under 37 CFR §11.9(b)

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Boston, Massachusetts 02109  
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<b>PTO-1449</b> (REV. 8-83)  <b>SUPPLEMENTAL          INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	<b>ATTY. DOCKET:</b> 2002834-0222	<b>IN RE          APPLICATION NO.:</b> 10/728,051
		<b>APPLICANT:</b> Caplan	
		<b>FILING DATE:</b> December 4, 2003	<b>GROUP:</b> 1644

#### U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	*6,221,648	Le Page et al.	April 24, 2001	435	252.3
	*5,888,799	Curtiss, III	March 30, 1999	435	252.3
	*5,834,246	Holmgren et al.	November 10, 1998	435	69.7
	*5,830,463	Duke et al.	November 3, 1998	424	93.51

#### U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	*WO 99/38978	International	05 August 1999		
	*WO 98/23763	International	04 June 1998		

#### OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	*Banks, et al., "Chemistry and Pharmacology of Honey-Bee Venom", <i>Venoms of the Hymenoptera</i> , 329-416, 1986.
	*Eko, et al., "New Strategies for Combination Vaccines Based on the Extended Recombinant Bacterial Ghost System", <i>Vaccine</i> , 17: 1643-1649, 1999.
	*Gentshev, et al., "Development of Antigen-Delivery Systems, Based on the Escherichia Coli Hemolysin Secretion Pathway", <i>Gene</i> , 179: 133-140, 1996.
	*Hess, et al., "Superior Efficacy of Secreted Over Somatic Antigen Display in Recombinant Salmonella Vaccine Induced Protection Against Listeriosis", <i>Proc. Natl. Acad. Sci. USA</i> , 93: 1458-1463, 1996.



<b>PTO-1449</b> <b>(REV. 8-83)</b>  <b>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT</b> <i>(Use several sheets if necessary)</i>	U.S. Department of Commerce Patent and Trademark Office	<b>ATTY. DOCKET:</b> 2002834-0222	<b>IN RE APPLICATION NO.:</b> 10/728,051
		<b>APPLICANT:</b> Caplan	
		<b>FILING DATE:</b> December 4, 2003	<b>GROUP:</b> 1644
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	
<b>EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			

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